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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/479,252	01/07/2000	Avi J. Ashkenazi	P0978P3C1	2825

7590 04/28/2004

GENENTECH INC  
Attn Diane L Marschang  
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South San Francisco, CA 94080-4990

EXAMINER
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BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 18, 19, 22 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 and 25 is/are allowed.
- 6) ☒ Claim(s) 1, 18, 19, and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Information Disclosure Statement (PCT 423)

4) ☐ Interview Summary (PTO 412)

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The Request for Continued Examination (RCE) filed on 15 January 2004 under 37 CFR 1.114 based on parent Application No. 09/479, 252 is acceptable and an RCE has been established. An action on the RCE follows.

### ***Status of Application, Amendments and/or Claims***

The amendment of 15 January 2004 has been entered in full. Claim 3 is amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3, 18-19, 22, and 25 are under consideration in the instant application.

### ***Sequence Compliance***

1. The Applicant's response to the Notice to Comply with Sequence Listing Requirements under 37 CFR §1.821 (15 January 2004) has been considered and is found persuasive. Therefore, the requirements set forth in the Notice to Comply (15 July 2003) are withdrawn.

### ***Withdrawn Objections and/or Rejections***

2. The supplemental information disclosure statement filed on 15 January 2004 has been considered.

### ***Claim Rejections - 35 USC § 102(a) and 35 USC § 102(e)***

3. Claims 1, 18-19, and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Wiley et al. (Immunity 3(6): 673-682, Dec. 1995). Claims 1, 18-19, 22, and 25 are also rejected under 35 U.S.C. 102(e) as being anticipated by Wiley et al. (U.S. patent 5,763,223). The basis

for this rejection is set forth at pg 3-4 of the previous Office Action of 15 July 2003 and at pg 3-4 of the Office Action of 13 November 2002.

It is noted that the claims are directed to an isolated soluble ligand polypeptide comprising amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1) and an isolated soluble ligand polypeptide consisting of amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1). The claims also recite a composition comprising the Apo-2 ligand polypeptide and a carrier. The claims recite that the composition useful for stimulating mammalian cell apoptosis comprises the Apo-2 ligand polypeptide. The claims also recite that the Apo-2 ligand polypeptide comprises an N-terminal methionine.

Applicant's arguments (15 January 2004), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that neither Wiley et al. reference teaches or suggests an Apo-2 ligand polypeptide having amino acid residues 91-281. Applicant contends that the Examiner has referred to various portions of the Wiley et al. references regarding the TRAIL protein. Applicant argues that it is clear there is no description in these references to a 91-281 form of the protein.

Applicant's arguments have been fully considered but are not found to be persuasive. It is noted to Applicant that, for example in claim 1, which recites "an isolated soluble ligand polypeptide *comprising* amino acid residues 91-281 of Figure 1A (SEQ ID NO: 1)", the term "comprising" is interpreted by the Examiner as open terminology. Therefore, the term "comprising" still allows the inclusion of other, larger nucleotide sequences that encode the protein, such as TRAIL protein of Wiley et al. (See MPEP § 2111.03; *Regents of the Univ. of*

*Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1573, 43 USPQ2d 1398, 1410 (Fed. Cir. 1997).)

Therefore, Wiley et al. teach an isolated soluble protein, designated TNF-related apoptosis-inducing ligand (TRAIL) that is 100% identical to the Apo-2 ligand polypeptide of the instant application *comprising* amino acids 91-281 of SEQ ID NO: 1 (see sequence alignments attached to the Office Action of 13 November 2002 as Appendices A and B; see pg 675, col 1 and amino acids 91-281 of Wiley et al.; see col 28-29, example 7 and amino acids 91-281 of U.S. patent 5,763,223; see also Figure 1A and amino acids 91-281 of SEQ ID NO: 1 of the instant application). The TRAIL protein identified by Wiley et al. that corresponds to amino acids 91-281 of SEQ ID NO: 1 of the instant application comprises an N-terminal methionine residue (see sequence alignments attached to the Office Action of 13 November 2002 as Appendices A and B; see amino acids 91-281 of Wiley et al. and U.S. patent 5,763,223). Additionally, Wiley et al. disclose that TRAIL induces apoptosis in many different types of cells, including mammalian cancer cells (pg 675-676; pg 678, col 1-2; Table 1 of Wiley et al.; col 26-27, example 5; col 29-30, example 8 ; Table 1 of U.S. patent 5,763,223). Wiley et al. treat the cells with conditioned supernatant from cells transfected with the soluble TRAIL construct, which is a composition (pg 680, ¶ 2 of Wiley et al.; col 28-29, example 7 of U.S. patent 5,763,223). Please note that this issue could be overcome by amending the claims to recite “An isolated soluble Apo-2 ligand polypeptide *consisting* of amino acid residues...”. However, this language is currently recited in claims 3 and 25.

### *Conclusion*

Claims 3 and 25 are allowable.

This is a continuation of applicant's earlier Application No. 09/479, 252. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Elizabeth C. Kemmfrer*

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